K081445 page 1 of 2

510 (k) Summary

AUG 11 2008 Page 1-of-2

1. Submitter Information

Company name	TaiDoc Technology Corporation
Contact person	Yuhua Chen
Address	6F, No.127, Wugong 2nd Rd., Wugu Township, Taipei County, 248, Taiwan
Phone	(886-2) 6625-8188
FAX	(886-2) 6625-0288
E-mail	yuhua.chen@taidoc.com

2. Name of Device

Trade Names	- Fora ComfortScan Ear Thermometer
Common Names	- Clinical electronic thermometer
Classification Names	- Class II devices - 21 CFR 880.2910, FLL-clinical electronic thermometer

3. Predicate Device

Trade/Proprietary Name:	Clever TD-1112 Ear/Skin/Surface IR Thermometer
Common/Usual Name:	- Clinical electronic thermometer
Manufacturer	TaiDoc Technology Corporation
510 (k) Number	K061800

4. Device Description

The Fora ComfortScan Ear Thermometer is characterized by measuring human body temperature and object's temperature in the ear canal and at the surface, respectively. It utilizes infrared technology to measure either infrared energy emitted from the eardrum and surrounding tissues or the surface radiation of the object when making a temperature measurement. It is able to detect skin temperature (only as a reference) when aimed at the target surface of human body.

5. Intended Use

The Fora ComfortScan Ear Thermometer is an electronic thermometer using an infrared sensor to detect human body temperature from the ear canal in the home. It is also available to detect object's surface temperature including human skin temperature.

6. Comparison to Predicate Device

Fora ComfortScan Ear Thermometer has equivalent technological characteristics and intended use as the Clever TD-1112 Ear/Skin/Surface IR Thermometer (K061800).

7. Performance Studies

The clinical and non-clinical studies were conducted to validate the effectiveness of use. The results were compliance to applicable voluntary standards includes ASTM E1965-98, as well as IEC 60601-1 and IEC 60601-1-2 requirements. For clinical results, differences were within clinical acceptability and repeatability was statistically and clinically acceptable.

8. Conclusion

Fora ComfortScan Ear Thermometer demonstrates satisfactory performance and are suitable for their intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 11 2008

Mr. Yuhua Chen
Regulatory Affairs Specialist
TaiDoc Technology Corporation
6F, No. 127, Wugong 2nd Road
Wugu Township, Taipei County
248, TAIWAN

Re: K081445
Trade/Device Name: Fora ComfortScan Ear Thermometer
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: May 19, 2008
Received: May 22, 2008

Dear Mr. Chen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

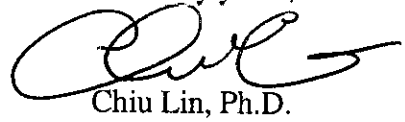
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K081445

Indications for Use

510(k) Number:

Device Name:
Fora ComfortScan Ear Thermometer

Indications for Use:

The Fora ComfortScan Ear Thermometer is an electronic thermometer using an infrared sensor to detect human body temperature from the ear canal on people of all ages and for use in the home. It is also available to detect object's surface temperature including human skin.

Prescription Use _____ And/Or Over the Counter Use __X.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Lana Ai for ADW
(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K081445

Division Sign-Off
Office of In Vitro Diagnostic Device Evaluation and Safety

510(k)_____

Page 1 of __1__